



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,555	08/29/2005	Erik Schwiebert	EL970613375US	7032

23859 7590 07/11/2006
NEEDLE & ROSENBERG, P.C.
SUITE 1000
999 PEACHTREE STREET
ATLANTA, GA 30309-3915

EXAMINER

PAK, JOHN D

ART UNIT	PAPER NUMBER
----------	--------------

1616

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/542,555

Applicant(s)

SCHWIEBERT ET AL.

Examiner

JOHN PAK

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 12, 13, 21-23, 34, 37, 38, 41-45, 48-52, 58, 61 and 64 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 12, 13, 21-23, 34, 37, 38, 41-45, 48-52, 58, 61 and 64 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Art Unit: 1616

Claims 1-3, 12-13, 21-23, 34, 37-38, 41-45, 48-52, 58, 61, 64 are pending in this application.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-3, 12-13, 21-23 and 34¹, drawn to a method of increasing Ca^{+2} levels in an airway epithelial cell or a method of treating airway disease comprising administering Zn^{+2} .

Group II, claims 37-38, 41, drawn to a composition comprising zinc, saline, low Na^{+} , enriched Ca^{+2} , and alkaline pH.

Group III, claims 42-43, drawn to a method of treating a bacterial infection or reducing inflammation in a subject comprising administering a composition comprising zinc, saline, low Na^{+} , enriched Ca^{+2} , and alkaline pH.

Group IV, claims 44, drawn to a method of treating polycystic kidney disease in a subject comprising administering a composition comprising zinc, saline, low Na^{+} , enriched Ca^{+2} , and alkaline pH.

Group V, claim 45, drawn to a method of treating endocrine disorder in a subject comprising administering a composition comprising zinc, saline, low Na^{+} , enriched Ca^{+2} , and alkaline pH.

Group VI, claims 48-52, 58, 61 and 64, drawn to a method of screening for an airway epithelial Ca^{+2} entry channel agonist.

The inventions listed as Groups I to VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

Under lack of unity rules, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” is defined as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The “contribution over the prior art” is considered with respect to novelty and inventive step. See PCT Rule 13.1 and 13.2; see also MPEP 1850.

Here, the prior art already discloses contacting various cells in the airway epithelia cell or cells in trachea, bronchi, bronchioles, or alveoli with a composition that contains zinc (i.e. Group I). See for example, US 5,840,278, claims 4 and 6 – see also from column 1, line 42 to column 2, line 7. Therefore, the actual method step of contacting P2X receptors on the cell or contacting cells in the trachea, bronchi, bronchioles, or alveoli with a composition that contains Zn^{+2} is not a technical feature that defines a contribution over the prior art.

The Inventions of Groups II to V are linked by the composition, which comprises zinc, saline, low Na^{+} , enriched Ca^{+2} , and alkaline pH. Again, US 5,840,278 discloses a substantially similar composition – high pH expected due to the alkaline sodium bicarbonate. Further, the three method inventions are divergent from one another in that polycystic kidney disease (Group IV) is a genetic disorder and endocrine disorder (Group V) is a disorder of hormones and glands, which are clearly divergent from mere treatment of bacterial infection or inflammation (Group III).

¹ Note, claim 34 depends on the canceled claim 24. Placement of claim 34 in Group I is based on the

The invention of Group VI is independent from the rest of the inventions in that it is a screening method for a therapeutic agent.

For these reasons, inventions of Groups I to VI are not so linked as to form a general inventive concept. The claims thereby lack a unity of invention as set forth above.

The examiner has required restriction between product (Group II) and process claims (Groups III, IV and V). Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

A telephone call was made to Ms. Cleveland on 6/27/2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

assumption that the intended base claim is 13 or 23. If that is not the case, applicant's subsequent amendment will dictate where claim 34 should be grouped.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

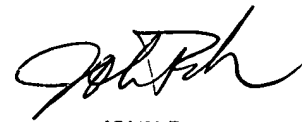
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JOHN PAK
PRIMARY EXAMINER
GROUP 1630